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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,518	04/25/2005	Thomas Dunker	Dunker, T. ET AL - 1 PCT	6031

25889 7590 09/17/2007

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EXAMINER	
STOUT, MICHAEL C	

ART UNIT	PAPER NUMBER
3709	

MAIL DATE	DELIVERY MODE
09/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,518	DUNKER ET AL.	
	Examiner	Art Unit	
	Michael C. Stout	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☒ Claim(s) *1,11 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 April 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *25 April 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/532518 filed 25 April 2005 and is a first action based on the merits of the application.

Drawings

1. Figures 2 and 3 should be designated by a legend such as --Prior Art— because only old art is shown and the written description designates that "Figures 2 and 3 show a known biopsy cannula 4 and trocar 19", (Page 8 Paragraph 2). See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. The device disclosed in claims 11 and 12 is not shown. Claimed material must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is

being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The abstract of the disclosure is objected to because biopsate is an uncommon term in the art and is not defined in the written description of the application. For the application to better be cross-referenced in the future the examiner recommends using a term such as "biopsy" or "bioptic."

The location of the term "removing" in the last sentence is a grammatical error. Correction is required. See MPEP § 608.01(b).

5. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

`Arrangement of the Specification`

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. **Each of the lettered items should appear in upper case, without underlining or bold type, as a section**

heading (emphasis added). If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The specification lacks a heading for each of the above sections (a)-(l). The headings should appear in uppercase, without underlining or bold type above their respective sections. Appropriate action is required.

Claim Objections

6. Claim 12 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 3 discloses a device having a wire with a pre-stress angle and Claim 12,

which is dependent on Claim 3 discloses a device with a wire not having a pre-stress angle. This removes a structure from claim 3 instead of further limiting the claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

7. The Claims 1 and 11 are objected to because they contain grammatical and idiomatic errors that appear to be a result of a literal translation. (i.e. Claim 1 reads "a wire with a beveling is arranged at the distal end of the wire" could be re-written as "a wire with beveling arranged at the distal end of said wire"). Appropriate correction is required.

8. Claims 11 and 12 objected to because they contain subject matter not disclosed in the specification. Claim 11 refers to the cross-section of the wire being dimensioned in such a manner that conditions a minimal pinch artefacture. Claim 12 refers to a tissue holding device without a pre-stress angle. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, a roughened surface with the cross-section of the wire being dimensioned in

such a manner to produce a minimal pinch artefacture, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. No description is given of a cross section that provides minimal "pinch" artifacture. Furthermore, one would also not know what cross-section would provide the described minimal "pinch" artifacture.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

12. Regarding claims 4,10, and 11 the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-4 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Paolo et al. US Patent 5,910,121 (hereinafter Paolo).

Regarding Claim 1 Paolo teaches:

A biopsy material holding device (intermediate cannula) for a biopsy cannula to perform transcutaneous biopsies of tissue, in particular hard tissue and bone marrow tissue (see Technical Field, Column 1, Paragraph 1) by means of a biopsy material holding device that can be inserted into the proximal end of a biopsy cannula (see Summary of the Invention, Lines 49-54 and Column 2, last Paragraph) and is inserted between the inner wall of a biopsy cannula and the tissue-removing cylinder (see Figure 5), wherein,

a wire (a resection means preferably a pair of thin plates 6, which can reasonably be interpreted as a wire, made of a suitably elastic material in particular spring-steel, see Column 3, lines 1-5 and 43-46) with a bevelling (the plates 6 have pointed extensions 6b, see Figure 1) is arranged at the distal end of the wire, "at" [examiner reads as: "in"] a biopsy material holding device and the wire having a Pre-stress angle (the pointed extensions 6b are bent in such a way as to close one against the other when the device is in non-operation condition, see Figure 6 and Column 3 Lines 1,2,56-59).

Regarding Claim 2 and 3 Paolo teaches:

A biopsy material holding device for a biopsy cannula according to claim 1 as set forth above -wherein,

the biopsy material holding device is made of a wire (6, see Figure 1) attached to a grip end (a barrel like element 5 located in the handle 3).

The wire is connected to the handle via the intermediate cannula, which is connected to the handle by means of a binding barrel like element 5, see Column 3 Lines 39-42 and Figure 1. Therefore, Paolo teaches a biopsy material holding device composed of a grip end with an attached extension shank (intermediate cannula 4) and that a wire (6) is fastened to the shank (see Figures 1 and 4).

Regarding Claim 4 Paolo teaches:

A biopsy material holding device for a biopsy cannula according to claim 1 as set forth above -wherein,

the wire has a tip with a bevelling and the tip with bevelling has,

a bevelling angle B of 5° to 85°, preferably 20°(Figure 4 shows a wire 6 that has a beveled tip 6b with an angle visibly between 5° and 85°),

and is facing the biopsy material cylinder (Figure 4 shows the upper part of the tip 6b facing the biopsy cylinder P).

Regarding Claim 8 Paolo teaches:

A biopsy material holding device for a biopsy cannula (4) according to claim 1 as set forth above -wherein,

the grip end can be locked into the grip end (the binding barrel – like element 5 is fastened to the handle 3, see Column 3 Lines 42-43) of the biopsy cannula (2, see Figure 1).

Regarding Claim 9 Paolo teaches:

A biopsy material holding device for a biopsy cannula according to claim 3 as set forth above –wherein,

the wire (thin metal plate 6, see Figure 1) is firmly connected to the distal end of the shank (intermediate cannula 4, see Figure 1) and a pre-stress angle between 1° and 90° is provided (Figure 6 shows the pre-stress angle of the wire 6 to be between 1° and 90°), according to the specific application.

Regarding Claim 10 Paolo teaches:

A biopsy material holding device for a biopsy cannula (4) according to claim 3 wherein,

the length of the wire (thin plate 6) is preferably 25 mm ("preferably" is indefinite language) and ends at the direct end of a known biopsy cannula (the wire 6 ends at the end of the cannula 2) after insertion of the shank (intermediate cannula 4) and locking of the grip end (barrel 5) into the grip of the biopsy cannula (handle 3) as stated in Column 3 Lines 37-42 and shown in Figure 1.

Regarding Claim 11 Paolo teaches:

A biopsy material holding device for a biopsy cannula according to claim 1 as set forth above, wherein the wire (thing plate 6) has a

roughened surface (tip 6b has a surface containing a certain roughness) and is shaped in an optional profile (one or two plate, see Figures 4 and 5) with the cross-section of the wire being dimensioned in such a manner that fastening of the wire at the distal end of the biopsy cannula conditions a minimal pinch artefacture (plates are joined to intermediate cannula 4, see Column 3 Line 52) with a diameter of preferably ca. 0.35 mm (the intermediate cannula has a diameter, Column 3 Line 37).

15. Claims 1,4,6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Scarfone et al. US Patent 5,385,151 (hereinafter Scarfone).

Regarding Claims 1 Scarfone teaches:

A biopsy material holding device for a biopsy cannula to perform transcutaneous biopsies of tissue, in particular hard tissue and bone marrow tissue by means of a biopsy material holding device that can be inserted into the proximal end of a biopsy cannula and is inserted between the inner wall of a biopsy cannula and the tissue-removing cylinder, wherein,

a wire (20, see Figure 3) with a bevelling is arranged at the distal end of the wire (21, see figure 1), "at" [examiner reads as: "in"] a biopsy material holding device and the wire having a Pre-stress angle (the top of the wire 20, in Figure 1 shows a pre-stress angle).

Regarding Claim 4 Scarfone teaches:

A biopsy material holding device for a biopsy cannula (14) according to claim 1 as set forth above wherein,

the wire (20) has a tip (21) with a bevelling (set forth above) and the tip with bevelling has a bevelling angle B of 5° to 85°, preferably 20°, and is facing the biopsy material cylinder (Figure 1 shows a wire 20 that has a beveled tip 21 with an angle visibly between 5° and 85°, and as the wire is retracted inside the cannula 14 and tissue enters the distal end of the cannula 15, the tip of the bevel 21 faces the biopsy tissue cylinder inside of the lumen of 14).

Regarding Claims 6 and 7 Scarfone teaches:

A biopsy material holding device for a biopsy cannula (14) according to claim 1 as set forth above wherein,

the wire (20) with a pre-stress angle (set forth above) is arranged at the centre of the grip end (18), with the pre-stress angle being between 1° and 90° (Figure 1 shows the wire located in the center of a grip with a pre-stress angle of approximately 90°) and the wire (20) has a length that corresponds to that of the biopsy cannula (14) and at ends at the latter's [Examiner assumes latter refers to the cannula] ending (Figure 1 shows a wire 20 that terminates at the distal end of the cannula 15).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paolo et al. US Patent 5,910,121 (hereinafter Paolo) in view of Fukuda et al. US Patent 6,322,581 B1 (hereinafter Fukuda).

Paolo anticipates the biopsy material holding device according to Claim 1 as set forth above wherein the device has a wire with bevelling. Paolo fails to teach the device wherein, the bevelling of the wire is either hollow ground, also known as concave, or bulged, also commonly known as convex (hollow ground creates a concave bevel surface and a bulge bevel leaves a convex or bulge bevel surface).

Fukuda teaches a various bevel finishes known in the art, for a suturing needle (wire) for medical use. Figures 4a thru 4e shows the bevelling on needles (wire) that are either hollow ground (52, Figure 4c) or bulged (51a, Figure 4b).

Because both Paolo and Fukuda teach wires having beveled surfaces, it would have been obvious to one having ordinary skill in the art to substitute one type of bevelling for another to achieve the predictable result of creating the tissue biopsy holding device taught by Paolo with the wire having a hollow ground or bulged bevel surface.

20. Claim 1,3 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgio US Patent 5,333,619 in view of Bookwalter US Patent 4,926,877.

Claim 12 has improper claim structure as stated above. Claim 12 cannot both have a pre-stressed angle (Claim1) and not have a pre-stressed angle (Claim 12). This rejection interprets claims 1,3, and 12 with no pre-stressed angle. Therefore, the Examiner has interpreted the claim to best describe the invention intended to be claimed, in view of the specification, as follows:

A biopsy material holding device for a biopsy cannula to perform transcutaneous biopsies of tissue, in particular hard tissue and bone marrow tissue by means of a biopsy material holding device that can be inserted into the proximal end of a biopsy cannula and is inserted between the inner wall of a biopsy cannula and the tissue-removing cylinder, wherein,

the biopsy material holding device is composed of a grip end with an attached extension shank and that a wire is fastened to the shank wherein,

bevelling is arranged at the distal end of the wire in the biopsy material holding device.

Regarding Claims 1,3 and 12 Burgio teaches:

A biopsy material holding device (see Figure 1) for a biopsy cannula to perform transcutaneous biopsies of tissue (see Abstract), in particular hard tissue and bone marrow tissue by means of a biopsy material holding device that can be inserted into the proximal end of a biopsy cannula and is inserted between the inner wall of a biopsy cannula and the tissue-removing cylinder, wherein,

the biopsy material holding device (see Figure 1) is composed of a grip end (a handle (not shown) ,see Column 1, Line 63) with an attached extension shank (handle-guide 1, see Column 2 Line 17) and that a wire (a thin plate 3, see Column 2 Line 18; in claim 2 Burgio describes the plate as having a circumference of less than 360°, therefore, this would include a plate that would have a circumference of only a few degrees and which can be reasonably interpreted as a wire) is fastened to the shank (see Figure 1) wherein,

Burgio does not teach a biopsy material holding device wherein bevelling is arranged at the distal end of the wire in the biopsy material holding device. However, Burgio does state, that the wire (thin plate 3) must have a thinness that is less than the space between the biopsy cylinder and the internal surface of the needle, which makes it possible for the plate to run along the needle's internal surface and insert itself between the cannula wall and the tissue biopsy cylinder. Figure 4 of the applicants invention shows a wire with bevelling arranged at the distal end of the wire wherein, the bevelling makes distal end of the wire thin enough

for it to be possible to inserted between the inner surface of the cannula (needle) and the tissue biopsy cylinder as required by Burgio.

Bookwalter teaches a biopsy material holding device for achieving minimum disruption to the tissue and insures a full section of biopsied tissue (see Column 1, Line 19 and Column 2 , Line 19) wherein, bevelling (a pointed tip 36, see Abstract and Figure 3) is arranged at the distal end of the wire (thin blade 14, see Figure 3) in the biopsy material holding device.

Since both Burgio and Bookwalter teach an apparatus to maintain tissue sample integrity in a biopsy device. It would have been obvious to one of ordinary skill in the art at the time the invention was made would have been motivated to biopsy holding device taught in Burgio with the pointed tip (bevelling) taught by Bookwalter because a pointed tip results in a thinner leading edge on things like thin plates (wires) which results in less disruption of the tissue and would facilitate the insertion of plate (wire) between the internal surface of the needle (cannula) and the tissue biopsy cylinder. Therefore the invention as a whole would have been prima facie obvious to one of ordinary sill in the art at the time the invention was made.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. Rubinstein et al. US Patent 5,462,062.

b. Janese US Patent 4,781,202.

c. Rubinstein US Patent 6,080,115.

d. Rubenstein et al. US Patent 5,885,226.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Stout whose telephone number is 571-270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JOSEPH DEL SOLE
SUPERVISORY PATENT EXAMINER
9/11/07